510(k) Summary

K090209

JUN - 2 2009

Applicant Contact Information:

Applicant:	Instrumentation Laboratory Co.
Address:	113 Hartwell Avenue Lexington, MA 02421
Contact Person:	Carol Marble, Regulatory Affairs Director
Phone Number:	781-861-4467
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Revision Date: April 23, 2009

Device Trade Names (Products Sold Separately):

HemosIL Liquid Heparin

HemosIL Heparin Calibrators

HemosIL LMW Heparin Controls

HemosIL UF Heparin Controls

Device Regulatory Information:

Heparin Assay:	Class II	Product Code: KFF	21 CFR 864.7525
Calibrators:	Class II	Product Code: JIS	21 CFR 862.1150
Controls:	Class II	Product Code: GGN	21 CFR 864.5425

Predicate Devices:

K980242	HemosIL Heparin
K030964	Calibration Plasma LMW Heparin
K030965	Control Plasma LMW Heparin

Device Intended Uses:

- HemosIL Liquid Heparin: Automated chromogenic assay for the quantitative determination of unfractionated heparin (UFH) and low molecular weight heparin (LMWH) activity in human citrated plasma on IL Coagulation Systems (ACL TOP® Family, ACL™ ELITE/ELITE PRO®/8/9/10000 and ACL Futura/ACL Advance Systems).
- HemosIL Heparin Calibrators: For the calibration of the HemosIL Liquid Heparin assay on IL Coagulation Systems (ACL TOP® Family, ACL™ ELITE/ ELITE PRO®/8/9/10000 and ACL Futura/ACL Advance Systems).
- HemosIL LMW Heparin Controls (Assayed): For the quality control of the HemosIL Liquid Heparin assay when testing for low molecular weight heparin (LMW) on IL Coagulation Systems (ACL TOP® Family, ACL™ ELITE/ ELITE PRO®/8/9/10000 and ACL Futura/ACL Advance Systems).
- HemosIL UF Heparin Controls (Assayed): For the quality control of the HemosIL Liquid Heparin assay when testing for unfractionated heparin (UFH) on IL Coagulation Systems (ACL TOP® Family, ACL™ ELITE/ ELITE PRO®/8/9/10000 and ACL Futura/ACL Advance Systems).

Device Descriptions:

- HemosIL Liquid Heparin

  One stage chromogenic assay based on a synthetic chromogenic substrate and on Factor Xa inactivation. Heparin levels in patient plasma are measured automatically on IL Coagulation Systems.

  Heparin is analyzed as a complex with antithrombin present in the sample. The concentration of this complex is dependent on the availability of the patient's endogenous antithrombin. When the Heparin – antithrombin complex is formed, two competing reactions take place.

  1. Factor Xa is neutralized by heparin-antithrombin complex.
  2. Residual Factor Xa is quantified with a synthetic chromogenic substrate. The paranitroaniline released is monitored kinetically at 405 nm and is inversely proportional to the heparin level in the sample.

- HemosIL Heparin Calibrators

  Lyophilized calibrators prepared from human citrated plasma by means of a dedicated process at three different heparin concentrations: 0, 0.8 and 2.0 IU/mL and are traceable to the WHO International Standards for LMW and UF Heparin.

- HemosIL LMW Heparin Controls (Assayed)

  Lyophilized controls prepared from human citrated plasma by means of a dedicated process at two different LMW heparin concentrations (low and high) for the assessment of precision and accuracy of the Liquid Heparin assay when testing for low molecular weight heparin.

- HemosIL UF Heparin Controls (Assayed)

  Lyophilized controls prepared from human citrated plasma by means of a dedicated process at two different UF heparin concentrations (low and high) for the assessment of precision and accuracy of the Liquid Heparin assay when testing for unfractionated heparin.

Statement of Technological Characteristics of the Device Compared to Predicate Devices:

- HemosIL Liquid Heparin is substantially equivalent to HemosIL Heparin (K980242) in performance and intended use.
- HemosIL Heparin Calibrators are substantially equivalent to Calibration Plasma LMW Heparin (K030964) in performance and intended use, except that the new calibrators are intended for use with both low molecular weight and unfractionated heparin testing.
- HemosIL LMW Heparin Controls and HemosIL UF Heparin Controls are substantially equivalent to Control Plasma LMW Heparin (K030965) in performance and intended use, except that HemosIL UF Heparin Controls are intended specifically for use with unfractionated heparin testing.

Substantial Equivalence Comparison Table:

Characteristic	New Device: HemosIL Liquid Heparin	Predicate Device: HemosIL Heparin (K980242)
Intended Use	Automated chromogenic assay for the quantitative determination of unfractionated heparin (UFH) and low molecular weight heparin (LMWH) activity in human citrated plasma on IL Coagulation Systems (ACL TOP® Family, ACL™ ELITE/ELITE PRO®/8/9/10000 and ACL Futura/ACL Advance Systems).	Same
Form	Liquid Substrate and FXa Reagent	Lyophilized Substrate and FXa Reagent
Test Principle	Chromogenic Assay	Same
Sample Type	Citrated Plasma	Same
Expected Values	To obtain an optimal effect with minimum risk of bleeding or thromboembolic complications the heparin activity should be in the range recommended by the heparin manufacturer.	Same
Linearity	ACL 8/9/1000/ELITE/ ELITE PRO Up to 2.0 IU/mL ACL Futura/ ACL Advance Up to 2.0 IU/mL ACL TOP Family Up to 2.0 IU/mL	ACL 8/9/1000/ELITE/ ELITE PRO Up to 1.0 IU/mL ACL Futura/ ACL Advance Up to 1.0 IU/mL ACL TOP Family Up to 1.1 IU/mL
Characteristic	**New Device: HemosIL Heparin Calibrators**	**Predicate Device: Calibration Plasma LMW Heparin (K030964)**
Intended Use	For the calibration of the HemosIL Liquid Heparin assay on IL Coagulation Systems (ACL TOP® Family, ACL™ ELITE/ELITE PRO®/8/9/10000 and ACL Futura/ACL Advance Systems).	For preparation of calibration curves for use in chromogenic heparin assays.
Form	Lyophilized	Same
Characteristic	**New Devices (Sold Separately): HemosIL LMW Heparin Controls HemosIL UF Heparin Controls**	**Predicate Device: Control Plasma LMW Heparin (K030965)**
Intended Use	LMWH Controls: For the quality control of the HemosIL Liquid Heparin assay when testing for low molecular weight heparin (LMW) on IL Coagulation Systems (ACL TOP® Family, ACL™ ELITE/ELITE PRO®/8/9/10000 and ACL Futura/ACL Advance Systems). UFH Controls: For the quality control of the HemosIL Liquid Heparin assay when testing for unfractionated heparin (UFH) on IL Coagulation Systems.	For the quality control of chromogenic heparin assays.
Form	Lyophilized	Same

Summary Performance Data:

Precision

Precision was assessed over multiple runs using the two levels of both UFH and LMWH Controls on representative IL Coagulation Systems:

ACL 8/9/1000/ELITE/ELITE PRO	Mean (IU/mL)	CV % (Within run)	CV % (Total)
UFH Low	0.39	4.0	6.7
UFH High	0.69	1.0	3.7
LMWH Low	0.49	5.5	5.7
LMWH High	1.31	3.3	4.0

ACL Futura/ACL Advance	Mean (IU/mL)	CV % (Within run)	CV % (Total)
UFH Low	0.41	4.4	4.4
UFH High	0.69	1.3	1.7
LMWH Low	0.56	2.5	3.5
LMWH High	1.37	1.1	1.6

ACL TOP Family	Mean (IU/mL)	CV % (Within run)	CV % (Total)
UFH Low	0.41	2.4	3.3
UFH High	0.68	1.0	1.6
LMWH Low	0.55	3.5	4.5
LMWH High	1.35	1.9	2.5

Method Comparison – In-house

An in-house method comparison study was performed, using samples from patients undergoing heparin therapy, to compare the performance of HemosIL Liquid Heparin versus the predicate device (HemosIL Heparin) on representative IL instrument platforms with the following results:

IL System	n	Slope	r
ACL ELITE	124	0.894	0.907
ACL Advance	152	1.067	0.946
ACL TOP	148	0.946	0.958

Method Comparison – Field Sites

Three field site studies were performed, using samples from patients undergoing heparin therapy, to compare the performance of HemosIL Liquid Heparin versus the predicate device (HemosIL Heparin) on representative IL instrument platforms with the following results:

IL System	n	Slope	r
ACL ELITE	114	1.032	0.949
ACL Advance	111	1.007	0.957
ACL TOP	81	0.952	0.978

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Instrumentation Laboratory Co.
c/o Ms. Carol Marble
Regulatory Affairs Director
113 Hartwell Avenue
Lexington, MA 02421

JUN - 2 2009

Re: k090209
Trade/Device Name: HemosIL Liquid Heparin, HemosIL Heparin Calibrators, HemosIL LMW Heparin Controls and HemosIL UF Heparin Controls
Regulation Number: 21 CFR §864.7525
Regulation Name: Heparin Assay
Regulatory Class: Class II
Product Code: KFF, JIS, GGN
Dated: April 23, 2009
Received: April 24, 2009

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090209

Device Name: HemosIL Liquid Heparin
HemosIL Heparin Calibrators
HemosIL LMW Heparin Controls
HemosIL UF Heparin Controls

Indications for Use:

- HemosIL Liquid Heparin: Automated chromogenic assay for the quantitative determination of unfractionated heparin (UFH) and low molecular weight heparin (LMWH) activity in human citrated plasma on IL Coagulation Systems (ACL TOP® Family, ACL™ ELITE/ ELITE PRO®/8/9/10000 and ACL Futura/ACL Advance Systems).
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For *in vitro* diagnostic use.

Prescription Use √ (Part 21 CFR 801 Subpart D) **OR** Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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